510 (K) SUMMARY

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Attn: H. David Shockley, jr., President
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Trade Name: IBC Gas Cell Component (Catalog Numbers 3000, 3010 & 3020)
Common Name: Blood Gas Flow Through Connectors
Classification Name: Sensor, Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
Product Code: (74DRY)
C.F.R. Section: 870.4410
Equivalent Device: CDI Gas Cell Component (Catalog Numbers 6620, 6630 & 6640)

Introduction

The IBC Gas Cell component was developed for use with the CDI Model 300 Blood Gas Monitoring System manufactured by 3M. The final geometry of the IBC Gas Cell component is identical to the final geometry of the 3M Gas Cell component, and both are fabricated from the same plastic materials. Performance of the IBC Gas Cell component within the CDI Model 300 Blood Gas Monitoring System is identical to the CDI Gas Cell component. The materials were evaluated for toxicity and sterilization compatability requirements as well as for function.

The CDI Model 300 Blood Gas Monitoring System employs three photochemical sensors to measure pO_2, pCO_2 and pH. Additionally, there is a thermo-electronic sensor for the direct measurement of temperature. The Electronics also contain calculation programs which use the measured parameters to determine O_2 Saturation (Venous side only) and Base Excess/$[HCO3]^-$ (Arterial side only). To complete the necessary calculations for these approximations, the Hemoglobin content is also required. This value is internally set at a Hematocrit of 25%. This value is corrected by the user during the initial and any subsequent on line recalibrations. The purpose of this report is to demonstrate the equivalence of the IBC Gas Cell component, as a substitute for the CDI Gas Cell component. The assumptions in the calculated values and any error which may be present as a result of the electronics, transducer or sensors is not to be evaluated. Consequently, only the measured parameters will be used in the functional analysis. The calculated values were recorded for general interest only.

The functional properties of the Gas Cells are determined by the final assembly geometry and the materials employed in construction, especially the two membrane materials. The final geometry of the IBC and CDI components are identical. Using chemical analysis, electron microscopy and information in the public domain, the membranes were sourced from the same supplier used by 3M.

Materials, Methods and Results

I. Functional Evaluation.

A. Assembly of Test Samples.

1. Twenty each frame /retainer assemblies were made using Standard Operating Procedures.

2. These assemblies were assembled to the $^3/_8$" flow through body .

3. The membrane guard was snapped into place and the assembly was leak tested.

4. Samples were subjected to the IBC standard sterilization cycle and placed in quarantine for 14 days.

5. Control samples of CDI manufactured products were purchased from commercial sources.

B. Test Equipment.

1. Instrumentation Laboratories Model 1420 Blood Gas Analyzer.

2. Instrumentation Laboratories Model 482 Co-Oximeter.

3. CDI Model 300 Blood Gas Monitor System (Monitor display, light head transducer, disposable photo-chemical sensors, and sensor calibrator).

4. IBC Model 1200 VenOsat Monitor.

5 Gambro Cardiovascular Heart-Lung Console Roller Pump.

6. Cincinnati Sub Zero Model 400 Heater/Cooler.

7. Cobe CML Oxygenators.

8. Heart Lung Tubing and connectors.

C. Test Circuit and Set up.

1. Assemble the circuit as shown in Test Assembly schematic drawing.

2. Using the $^1/_4$" spike, prime the integral hard shell reservoir on the Cobe CML with Human Blood which has been typed and cross matched and preserved with Acid Citrate Dextrose A U.S.P.. Fill to a level which is approximately 1" above the Heat Exchanger (Approximately four units).

3. Using the Roller Pump Head, prime the oxygenator circuit with a clamp at point B. After the oxygenator is fully primed, move the clamp to Point A and continue to prime the oxygenator bypass line. Recirculate at 2 liters per minute.

4. Calibrate the CDI Gas Cell Sensors per the operating instructions.

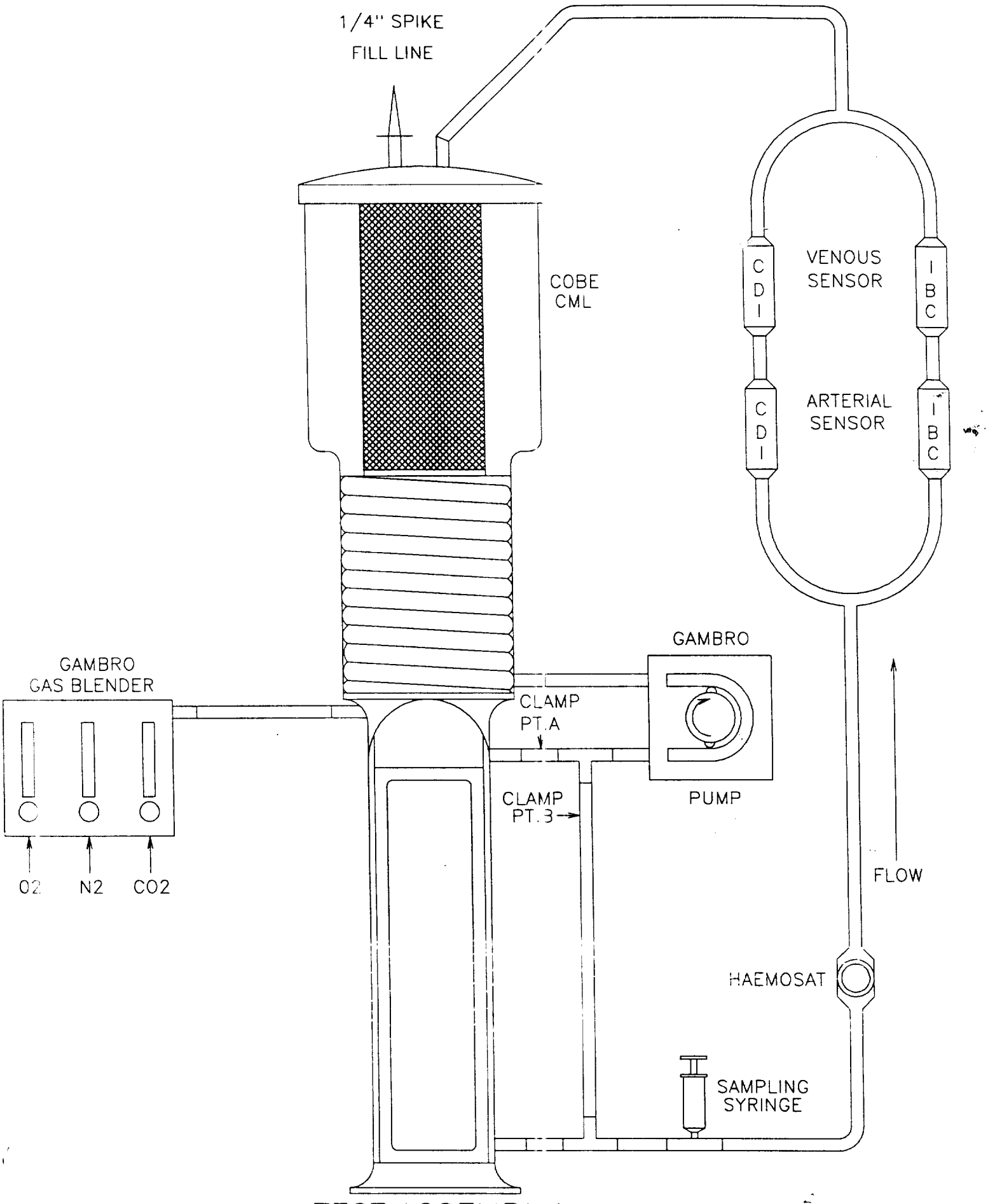
5. Draw a test sample for the Blood Gas Analyzer and C0-Oximeter.

6. Using the oxygenator and Gas Blender adjust the blood to physiological conditions. Using 5% Sodium Bicarbonate in Normal Saline, adjust the pH to physiological levels.

D. Test Procedure.

1. Stop Pump Head to discontinue the recirculation.

2. Remove the membrane guard from the two CDI Gas



TEST ASSEMBLY

Cells and snap the calibrated sensors in place and attach the light head transducers.

3. Resume the operation of the Pump Head, setting a flow rate of 3.5 Liters per Minute.

4. Observe the readings in the CDI Monitor Display and the IBC VenOsat Monitor Display. If the readings are suitable and stable, Take a sample from the sample port and run it through the IL Blood Gas Analyzer and the IL Co-Oximeter. Simultaneously document the readings from both on-line monitors and press the recalibration button on the CDI Model 300 Monitor.

5. Recalibrate the monitor using the values obtained from the IL Co-Oximeter and Blood Gas Analyzer.

6. Move the clamp from Point A to Point B and, using the Gas Blender, alter the blood gases. Move the clamp from Point B back to Point A and wait for the on line readings to stabilize(5 minutes).

7. After the five minute period, draw another blood sample for the IL analyzers and document the readings on the CDI monitor. Repeat this procedure (steps 6. and 7.) until ten different readings are obtained.

8. Stop the Pump Head .

9. Calibrate two fresh Gas Stat Sensors and snap them into the IBC flow through cells.

10. Resume operation of the Roller Pump at a flow rate of 3.5 Liters per Minute.

11. Repeat steps 4., 5., 6. and 7. and then stop the pump and change the circuit using fresh disposables and blood for

the next test samples.

12. Repeat the test using IBC manufactured components first and CDI manufactured components second.

13. Follow this alternating procedure for ten runs (until ten pairs of gas cells have been tested from both manufacturers).

E. Data Collection and Treatment.

1. Record each CDI reading along with the appropriate IL readings.

2. Calculate the mean variance and mean per cent variance for each test sample and tabulate at the bottom of the log sheets.

3. Tabulate the mean error and % error from each of the ten runs on the Gas Stat Test Data Analysis Log.

4. Calculate the average error for all 200 data points for all measured and calculated parameters. Record these calculations on the Analysis log.

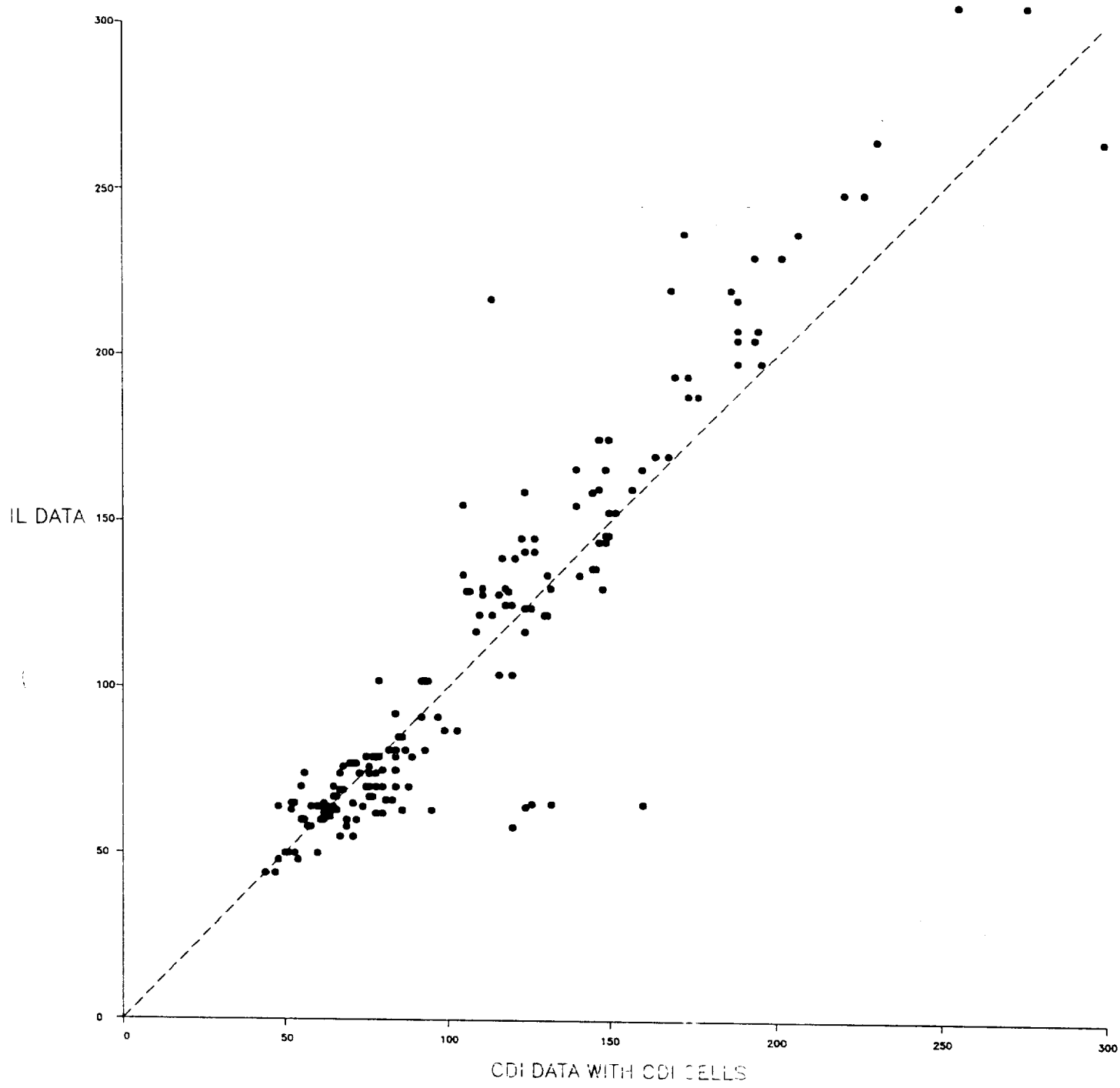
5. Construct a graph for comparison of all 200 pairs of readings for the measured parameters, pO_2, pCO_2 and pH, obtained from testing components of both manufacturers.

6. The following pages contain summary of the findings.

CD .S CELL GAS STAT TES .TA ANALYSIS

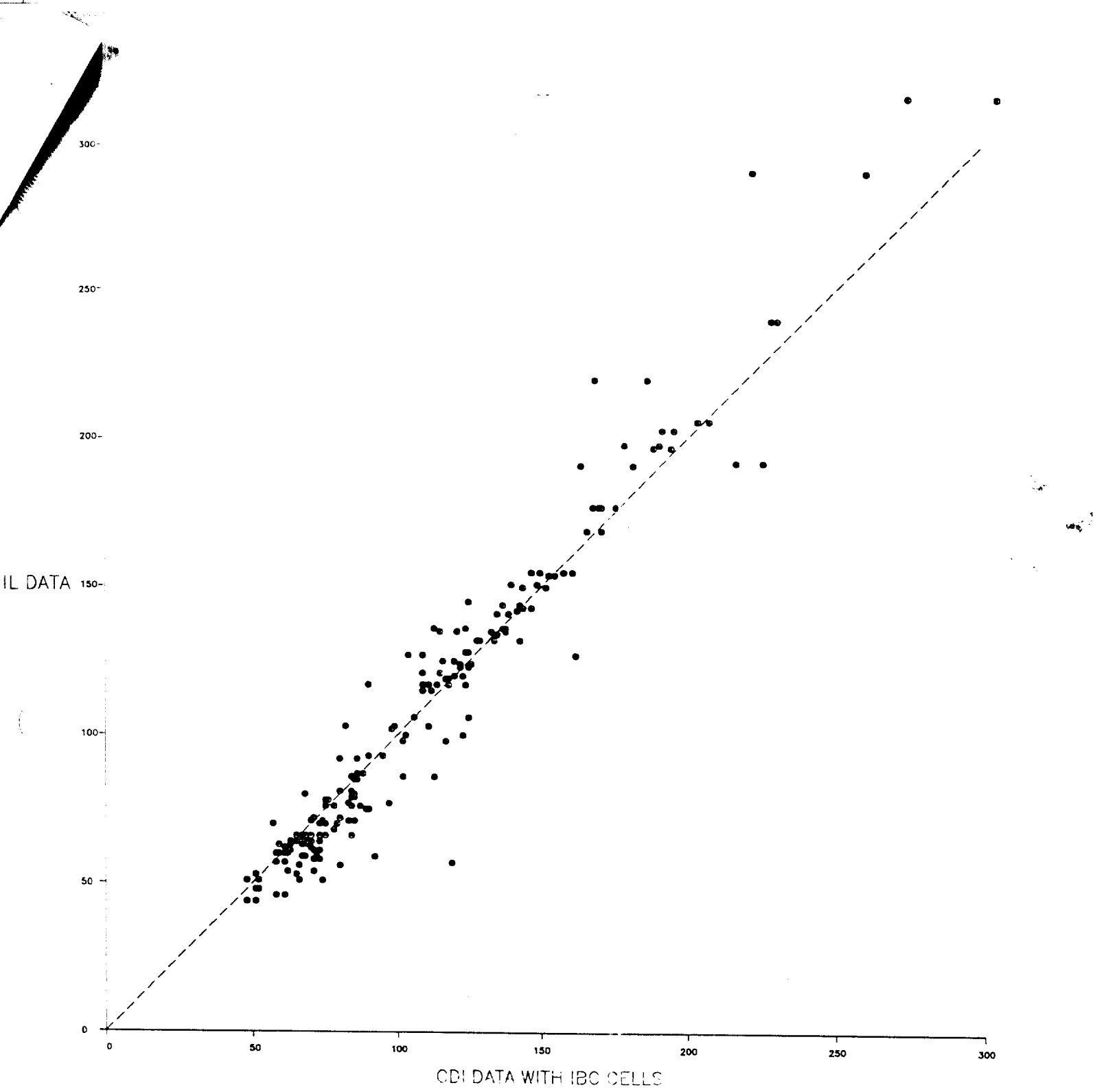
SAMPLE	pO2	pCO2	pH	[HCO3]	BE	SAT
CDI #1 ERROR	-11	2	-0.01	1	0.0	6
CDI #1 % ERR	-10%	4%	0%	3%	-1%	7%
CDI #2 ERROR	-6	1	0.00	1	0.6	1
CDI #2 % ERR	-6%	1%	0%	5%	-8%	2%
CDI #3 ERROR	-3	1	-0.03	-2	-2.5	-2
CDI #3 % ERR	-3%	1%	0%	-8%	60%	-2%
CDI #4 ERROR	5	7	-0.03	-2	-3.8	-1
CDI #4 % ERR	4%	15%	0%	-9%	-408%	-1%
CDI #5 ERROR	2	1	0.01	0	0.4	-9.1
CDI #5 % ERR	1%	2%	0%	1%	-6%	-10%
CDI #6 ERROR	-4	0	-0.01	-1	-0.8	1.6
CDI #6 % ERR	-3%	1%	0%	-4%	17%	2%
CDI #7 ERROR	-1	2	0.00	1	0.7	-8
CDI #7 % ERR	-1%	4%	0%	5%	-9%	-9%
CDI #8 ERROR	-9	2	0.00	1	0.7	-3
CDI #8 % ERR	-8%	6%	0%	4%	-18%	-4%
CDI #9 ERROR	-1	-2	0.00	-1	-1.0	-6
CDI #9 % ERR	-1%	-4%	0%	-5%	12%	-7%
CDI #10 ERROR	-5	1	-0.02	-2	-2.5	-2
CDI #10 % ERR	-5%	1%	0%	-8%	60%	-2%
AVERAGE ERROR	-3	1	-0.01	0	-0.8	-2
AVG % ERROR	-3%	3%	0%	-1%	-30%	-2%

SAMPLE	pO2	pCO2	pH	[HCO3]	BE	SAT
IBC #1 ERROR	-7	1	0.02	2	2.1	-4
IBC #1 % ERR	-6%	1%	0%	11%	-36%	-4%
IBC #2 ERROR	-1	2	-0.03	-1	-2.3	-1
IBC #2 % ERR	-1%	4%	0%	-5%	39%	-1%
IBC #3 ERROR	3	0	0.00	0	0.11	-8
IBC #3 % ERR	3%	-1%	0%	0%	-4%	-9%
IBC #4 ERROR	8	1	0.00	-1	-0.9	-14
IBC #4 % ERR	7%	3%	0%	-3%	25%	-16%
IBC #5 ERROR	-1	0	-0.01	-1	-0.6	-0.4
IBC #5 % ERR	-1%	0%	0%	-2%	14%	0%
IBC #6 ERROR	9	0	-0.02	-2	-0.5	-10.3
IBC #6 % ERR	10%	-1%	0%	-8%	12%	-12%
IBC #7 ERROR	3	-0.6	0.05	3	3.8	-8
IBC #7 % ERR	3%	-1%	1%	16%	-98%	-9%
IBC #8 ERROR	-5	2	0.00	1	0.5	-12
IBC #8 % ERR	-4%	5%	0%	4%	-8%	-13%
IBC #9 ERROR	-1	0	0.00	-1.4	-0.7	-6
IBC #9 % ERR	-1%	1%	0%	-7%	8%	-7%
IBC #10 ERROR	-2	1	-0.02	-2	-2.5	-2
IBC #10 % ERR	-2%	1%	0%	-8%	60%	-2%
AVERAGE ERROR	1	1	0.00	0	-0.1	-6
AVG % ERROR	1%	1%	0%	0%	1%	-7%



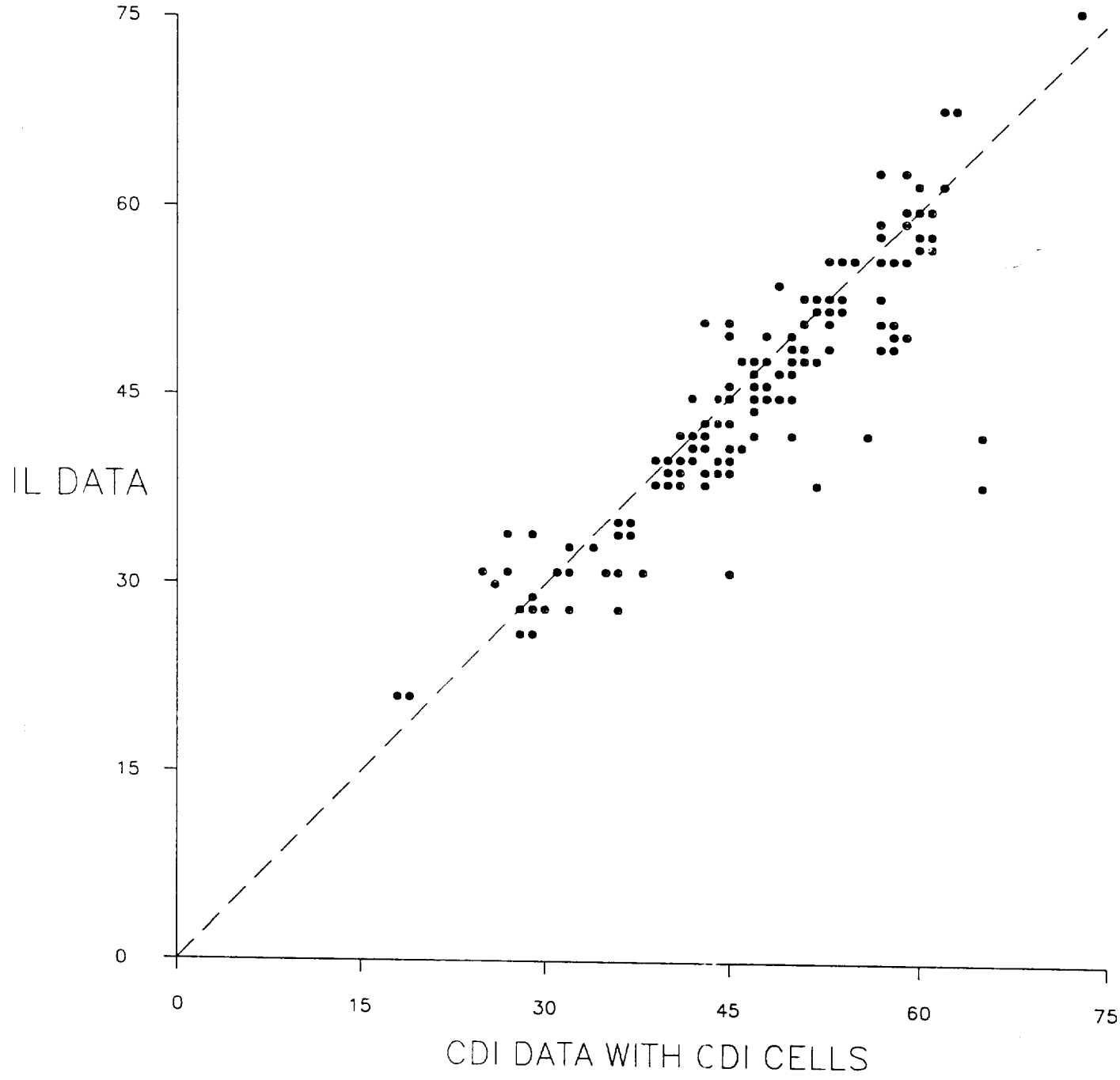
GRAPH 1

pO2 COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING CDI CELLS



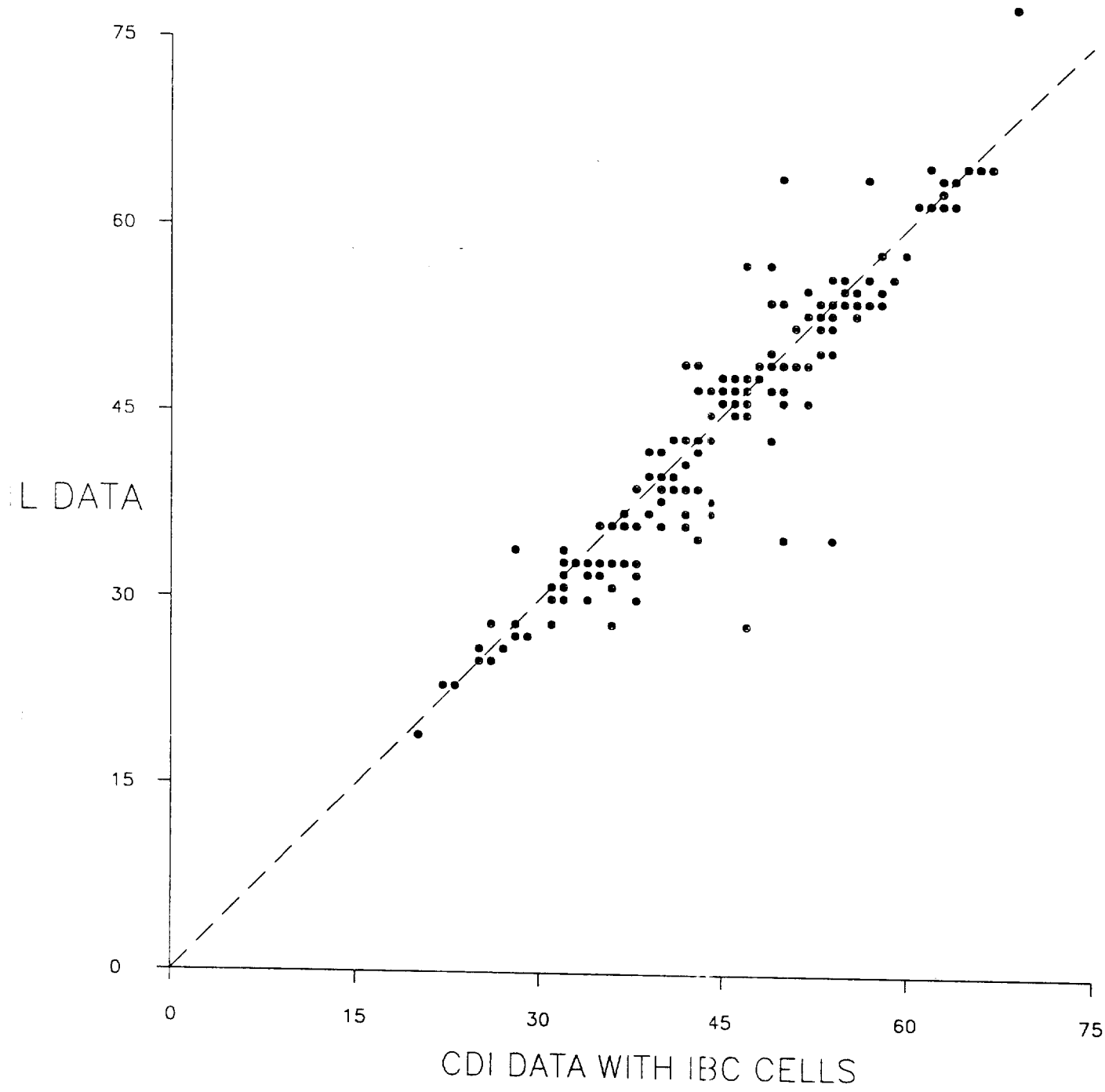
GRAPH 2

pO2 COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING IBC CELLS



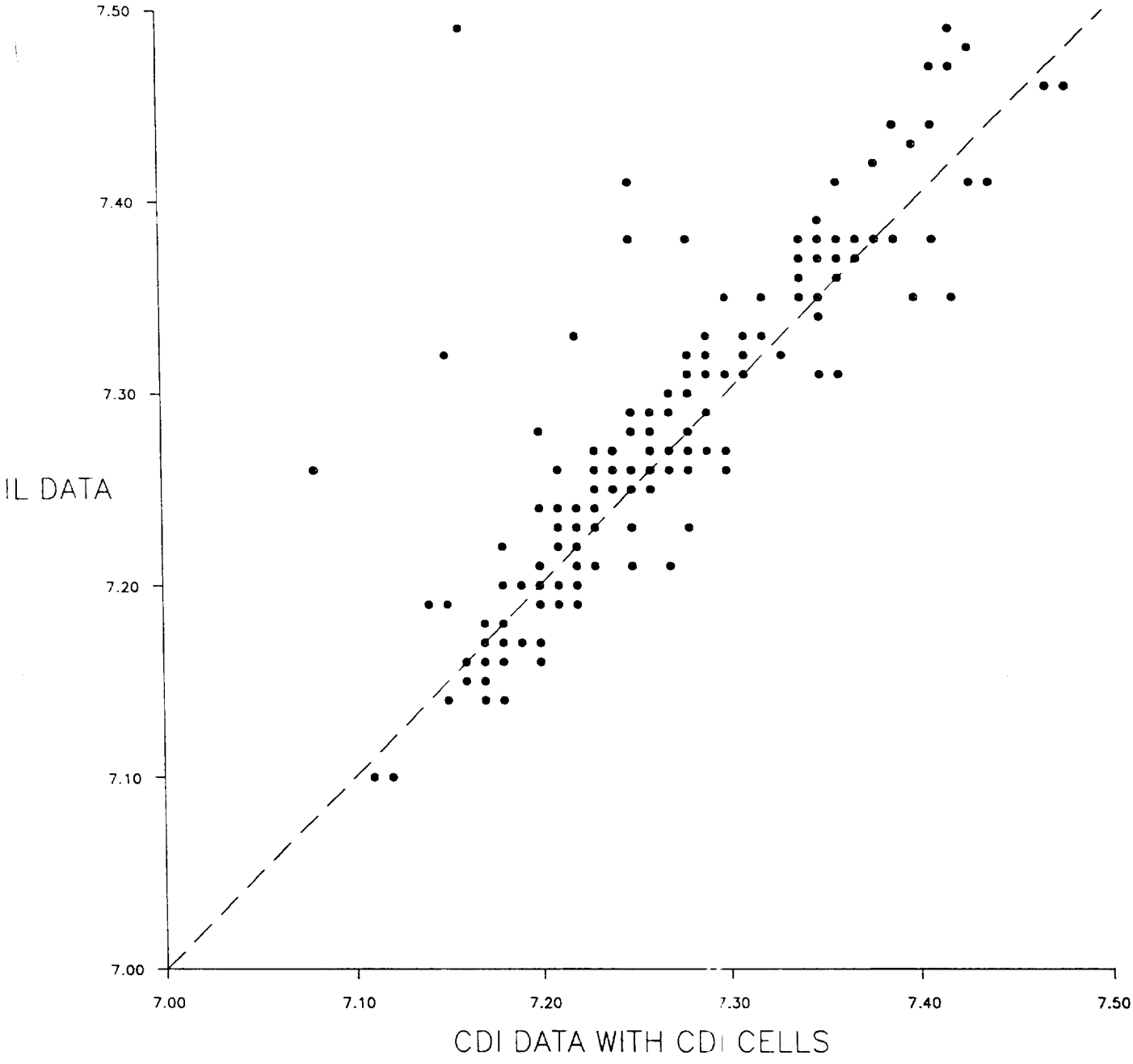
GRAPH 3

pCO2 COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING CDI CELLS



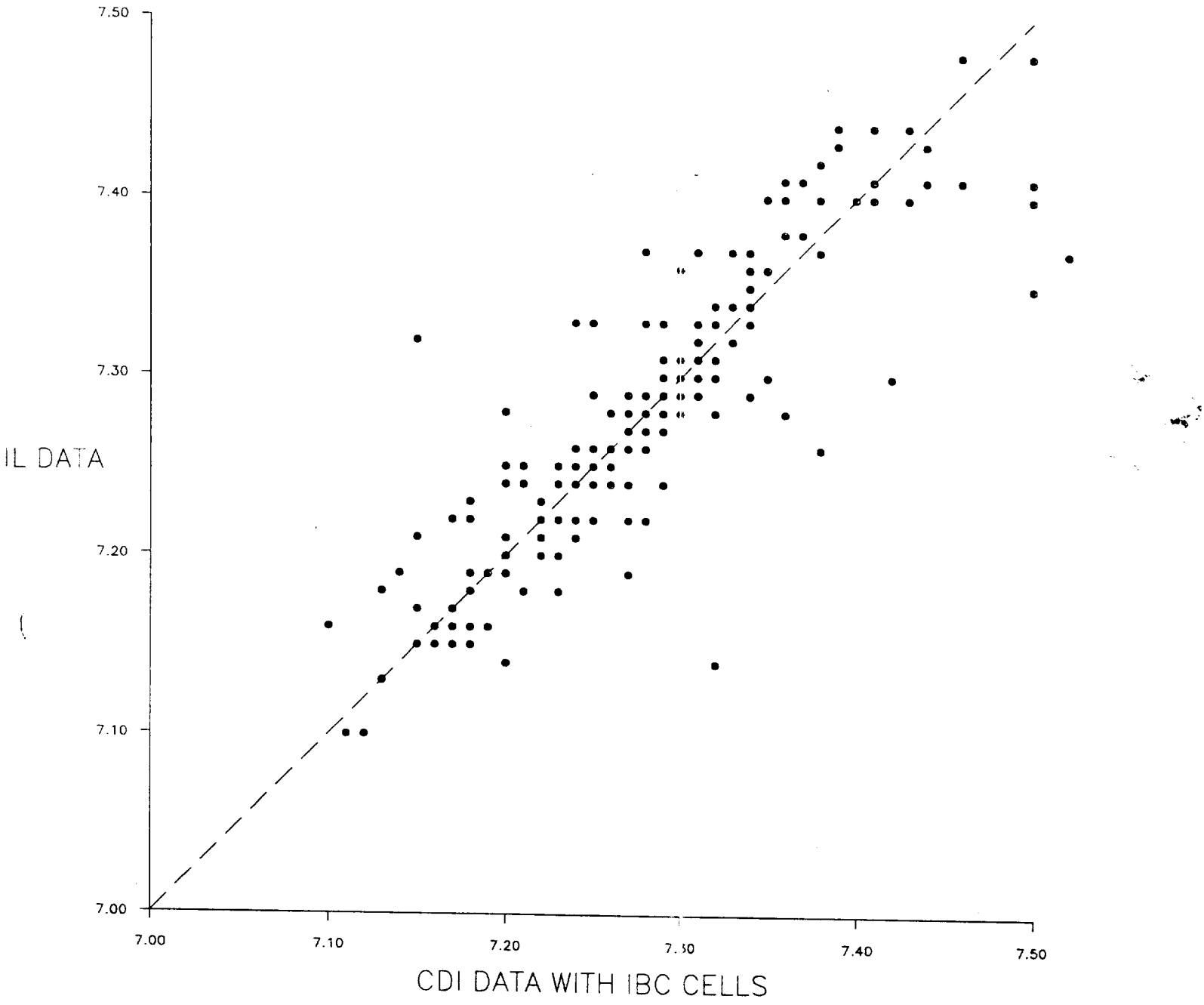
GRAPH 4

pCO2 COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING IBC CELLS



GRAPH 5

pH COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING CDI CELLS



GRAPH 6

pH COMPARISON BETWEEN INSTRUMENTATION LABORATORIES AND CDI USING IBC CELLS

II Assembly Integrity.

A. Assembly Leak Test.

1. Assemble sixty IBC Gas Cell Components using Standard Operating Procedure, using the clear and opaque membranes as designed.

2. Subject the assemblies to the IBC standard sterilization procedure and allow a fourteen day degassing period.

3. Store twenty of the assemblies 24 hrs at 4°C, 25°C and 60°C.

4. Place the assemblies to fit loosely in a drum type container. Shake the container in a paint mixer for 5 minutes.

5. Package the assemblies per Standard Operating Procedure and drop from a height of fifteen feet ten times.

6. Pressurize the assemblies at 10 P.S.I. under water and check for leaks with the membrane support in place.

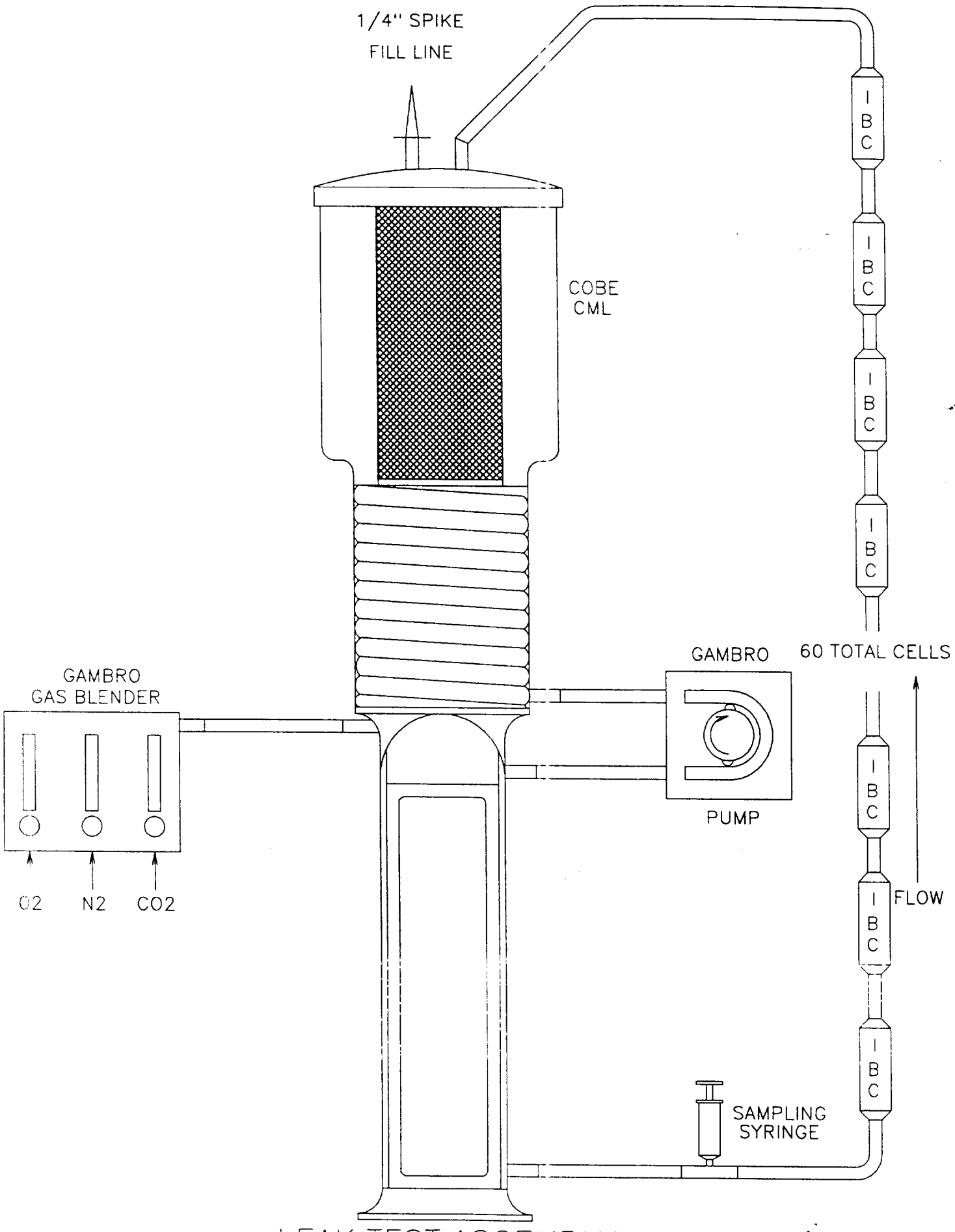
7. Remove the membrane support clip from the assemblies, fully wet the opaque membrane to establish the bubble point and check for leaks at 10 P.S.I. under water.

8. No leaks were detected.

B. Clinical Simulation Leak Test.

1. Remove the sixty samples from the Assembly leak test section and allow them to dry for use in this section.

2. Assemble the components in series using a Cobe CML



LEAK TEST ASSEMBLY

Membrane Oxygenator and extracorporeal tubing and connectors as shown in Leak Test Assembly schematic drawing.

3. Prime the circuit with Bovine Blood which has been freshly collected and preserved in ACD A U.S.P. for less than twenty four hours.

4. Recirculate at 6 Liters per Minute flow rate for one hour at 37°C, for four hours at 25°C and for one hour at 37°C.

5. Stop the pump, remove the Membrane Support Guards and observe for leaks. There should be a straw colored plasma present on top of the membrane but no cellular (Red) components.

6. No leaks were detected.

C. Sensor Seal Integrity.

1. Select ten samples from the Assembly leak test section.

2. Remove the membranes completely using a scalpel.

3. Insert the used sensors from the functional test section.

4. Pressurize under water at 10 P.S.I. and observe for leaks.

5. No leaks were detected.

III. Toxicity Testing.

A. U.S.P. Plastic Class 6 Testing.

1. Prepare plastic samples of the clear plastic housing material, the elastomer seal material, the opaque white membrane and the clear membrane as needed.

2. Subject the samples to the IBC standard ethylene oxide sterilization cycle.

3. Allow 14 days for aeration.

4. Provide samples to an independent laboratory for U.S.P. Testing per current GLP's.

5. The samples were found to meet U.S.P. Plastic Class 6.

B. Hemolysis.

1. Assemble and sterilize 10 IBC gas cell components and allow 14 days for aeration.

2. Place all ten connectors in series using a Cobe CML Membrane Oxygenator and extracorporeal tubing and connectors as shown in the Hemolysis schematic diaphragm.

3. Prime the circuit with fresh Bovine blood that is preserved in ACD A U.S.P. and stored for less than 24 hours.

4. Recirculate at 6 Liters per minute for 6 Hours at 37°C.

5. Repeat the test with 10 CDI gas cell components.

6. Centrifuge a representative sample from each test run and from the uncirculated blood.

7. Observe the plasma fraction for signs of free hemoglobin. It should be straw colored if free of hemolysis induced plasma hemoglobin. Plasma hemoglobin will give the plasma a distinct pink to red tint.

8. The samples were found to be Non-Hemolytic.

2. Subject the samples to the IBC standard ethylene oxide sterilization cycle.

3. Allow 14 days for aeration.

4. Provide samples to an independent laboratory for U.S.P. Testing per current GLP's.

5. The samples were found to meet U.S.P. Plastic Class 6.

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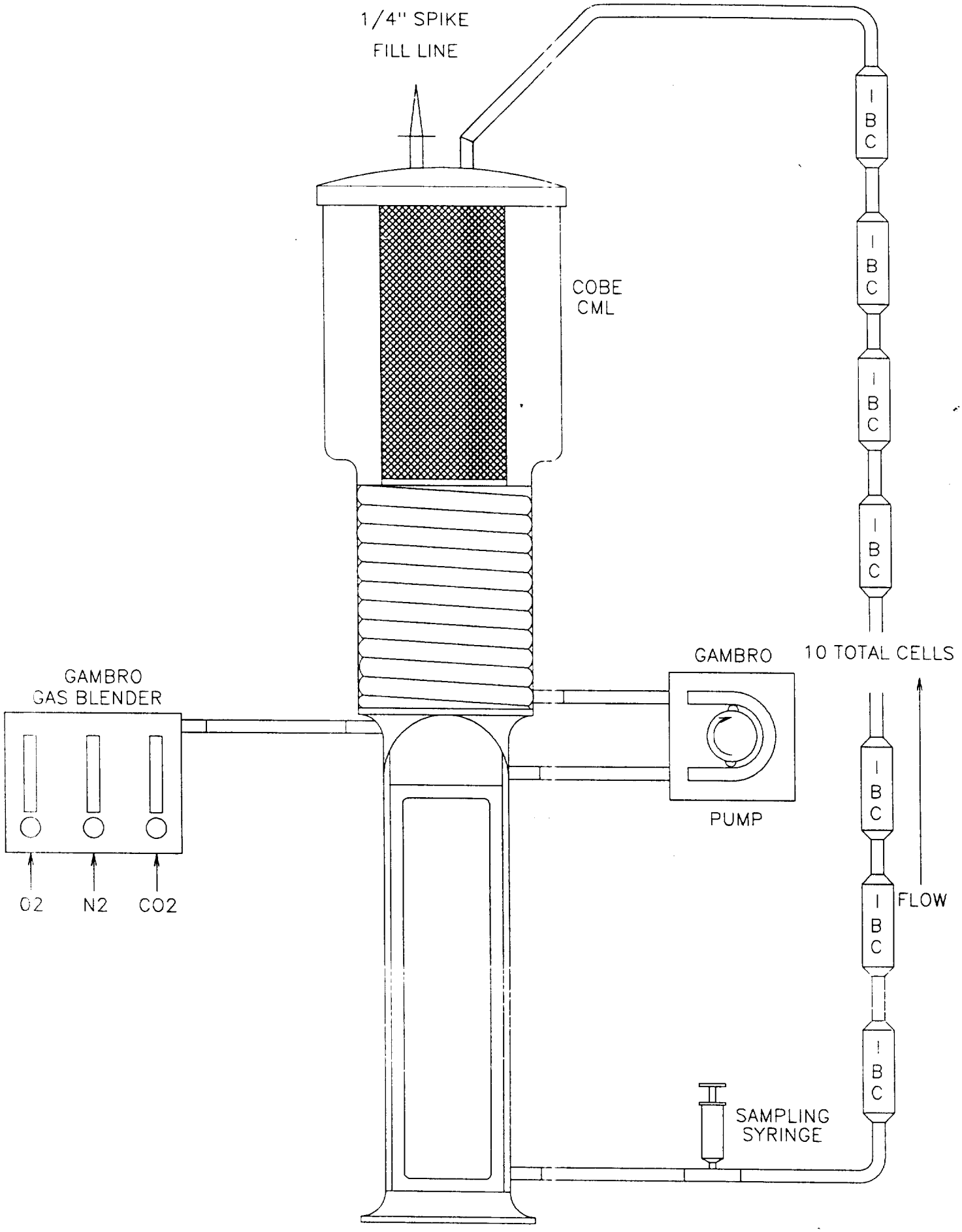

HEMOLYSIS TEST ASSEMBLY

IV. Bioburden and Sterilization Evaluation.

A. Bioburden. Per C.G. Laboratories standard methods and GLP's, the samples were found to contain an average bioburden of 20 colony forming units per assembly.

B. Ethylene Oxide Residues. Per C. G. Laboratories standard methods and GLP's, the following Ethylene Oxide Residue levels were noted.

Ethylene Oxide	Ethylene Glycol	Ethylene Chlorhydrin
<25 ppm	<250 ppm	<25 ppm

C. Pyrogenicity. Per the United States Pharmacopeia, the samples were found to be Non-Pyrogenic, U.S.P.

Discussion

Functionally, the CDI Model 300 Blood Gas Monitoring System is reasonably accurate when used in accordance with the Operator's Manual. The primary variations seen during the testing were attributed to variations from sensor to sensor. The calibration of the sensor using calibration gases and the buffer solution would in most cases yield reasonable results. The device became exceedingly accurate after one on line recalibration. The largest variations as seen on the graphs are generally attributable to the first readings taken after going on-line.

The oxygen sensor is located on the clear membrane window. This membrane is non porous and also susceptible to the greatest error. This was particularly noticeable at high pO_2 levels. This is probably attributable to the lack of porosity. This sensor, however does require the clarity of the membrane to function properly. The Model 400 employs a porous membrane which is clear when wetted. The apparent superiority of the IBC cells relative to the CDI cells is a result of a greater number of high readings with CDI. The products actually showed no significant difference relative to the pO_2 readings.

The remainder of the sensors are located on the opaque membrane. This membrane is microporous (0.2 u) and allows a free flow of ions and gases through it while maintaining a sterile barrier. The free flow of Hydrogen ions to the sensor provides the stimulus that allows the transducer to measure pH. On the arterial channel, this pH

The assemblies of IBC product were found to be sound and free of leaks. The assembly methods yield bond strengths far in excess of the requirements that might be encountered in a clinical setting. The bond between the membrane and the support frame was evaluated with the clear membrane very closely for two reasons. First, the opaque membrane is porous and easily bonded to the polycarbonate with the UV adhesive we selected. Secondly, the clear membrane is made of a material that is inherently reluctant to bond with most adhesives.

The materials, four in all, used to fabricate the IBC Gas Cell Component all meet U.S.P. Plastic Class 6 Testing. The materials are non toxic after Ethylene Oxide Sterilization and meet the FDA recognized standards for ethylene oxide residues after 14 day aeration. The fabrication methods result in low bioburden assuring adequate margins of safety in normally validated ethylene oxide sterilization cycles.

The hemolysis testing was designed to be five times more stringent than the exposure the blood would get in the most severe clinical instance. In spite of this extreme protocol, there was no detectable free hemoglobin in the plasma fraction. The use of the IBC product in place of the CDI product will result in no differences relative to trauma to the blood. While hemolysis is not the only form of damage that the blood might encounter in the extracorporeal setting, it is generally recognized as representative of the level of trauma the blood is experiencing.

Conclusion

1. The IBC Gas Cell Component was tested in comparison with the CDI Gas Cell Component within the CDI Model 300 Blood Gas Monitoring System. The two products were identical relative to performance and function.

2. The IBC Gas Cell component was tested for its integrity and found to be sound and free of leaks and assembly weaknesses. The product is safe for its intended use in extracorporeal circuits.

3. The IBC Gas Cell component was evaluated for Toxicity and found to be nontoxic. It is suitable for use in the intended extracorporeal applications.

4. The IBC Gas Cell component was evaluated for its compatibility with Ethylene Oxide Sterilization. The IBC component may be safely used in tubing packs which are

gas sterilized and may be sold after gas sterilization for insertion into the appropriate tubing line by the Cardiovascular surgical team.

5. The IBC Gas Cell component is not hemolytic when used in the extracorporeal circuit in accordance with normal clinical practice.

6. The membranes used in the IBC Gas Cell component are identical to those used in the CDI product.

7. The IBC Gas Cell Component may be substituted for the CDI Gas Cell Component in the construction of Extracorporeal Custom Tubing Packs either by the manufacturer of such packs or by the end user to modify his or her pack as needed.